510(k) SUMMARY

Blackstone Medical's Unity LX™ Anterolateral Lumbar Plate Fixation System

SUBMITTER: Blackstone Medical, Inc.

ADDRESS: 1211 Hamburg Turnpike
Suite 300
Wayne, NJ 07470

PHONE: (973) 406-2847
FAX: (973) 633-6811

CONTACT PERSON: Martin G. Sprunck
Senior Regulatory Affairs Specialist

TRADE NAME: Unity LX™ Anterolateral Lumbar Plate Fixation System

COMMON NAME: Spinal Fixation System

CLASSIFICATION NAME: Spinal Intervertebral Body Fixation Orthosis,
21 CFR 888.3060

PRODUCT CODE: KWQ – Appliance, Fixation, Spinal Intervertebral Body

PREDICATE DEVICES: Blackstone Medical, Inc. Unity™ Anterior Lumbar Plate Fixation System, (K043548 SE 6-14- 2005)
Synthes Anterior Tension Band System (K022791 SE 11-13-2002)

Intended Use / Indications for Use

The Unity LX™ Anterolateral Lumbar Plate Fixation System is indicated for use as an anteriorly or anterolaterally placed supplemental fixation device for the lumbar region of the spine (L1-L5) above the bifurcation of the vascular structures. When properly used, this system will help provide temporary stabilization until a solid spinal fusion develops. Specific indications include:

1) Degenerative disc disease (defined as back pain of discogenic origin with degenerative disc confirmed by history and radiographic studies)
2) Pseudoarthrosis
3) Spondylolysis
4) Spondylolisthesis
5) Fracture
6) Neoplastic disease
7) Unsuccessful previous fusion surgery
8) Lordotic deformities of the spine
9) Idiopathic thoracolumbar or lumbar scoliosis
10) Deformities (i.e., scoliosis, kyphosis, and/or lordosis) associated with deficient posterior elements such as that resulting from laminectomy, spina bifida, or myelomenigocele
11) Neuromuscular deformity (i.e., scoliosis, lordosis, and/or kyphosis) associated with pelvic obliquity

Technological Characteristics

The Unity LX Anterolateral Lumbar Fixation Plate consists of:

1) A base plate
2) A cover plate with locking setscrew
3) Bone screws

Performance Data

Mechanical testing of the Blackstone Medical Unity LX Anterolateral Lumbar Fixation Plate System was conducted which demonstrates that the system is substantially equivalent to predicate devices that have the same intended use, similar indications, technological characteristics and principles of operation.

Substantial Equivalence

The Unity LX Anterolateral System, the Unity Anterior System and the Synthes ATB System have the same intended use and similar indications, technological characteristics and principles of operation. The only technological differences between the Unity LX Anterolateral Lumbar Fixation Plate and its predicates are minor dimensional characteristics and have been addressed with side-by-side mechanical verification testing. These differences do not present any new issues of safety or effectiveness, therefore, the Unity LX Anterolateral Lumbar Fixation Plate is substantially equivalent to its predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 24 2006

Mr. Martin Sprunck
Senior Regulatory Affairs Specialist
Blackstone Medical, Inc.
1211 Hamburg Turnpike, Suite 300
Wayne, New Jersey 07470

Re: K061229
Trade/Device Name: Unity LX Anterolateral Lumbar Plate System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: Class II
Product Codes: KWQ
Dated: July 19, 2006
Received: July 20, 2006

Dear Mr. Sprunck:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Barbara Brenner

Mark N. Melkerson, M.S.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K061229

Device Name: Unity LX™ Anterolateral Lumbar Plate Fixation System

Indications for Use:

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Prescription Use __X__ (Part 21 C.F.R. 801 Subpart D) AND/OR Over-The-Counter Use____ (21 C.F.R. 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Bredin

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K061229